

Exhibit A

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

B.F., et al.,)
)
)
Plaintiffs,)
)
)
v.) No. 4:12-CV-1760-CAS
)
)
ABBOTT LABORATORIES, INC., et al.,)
)
)
Defendants.)

PRETRIAL CONFERENCE

BEFORE THE HONORABLE CHARLES A. SHAW
UNITED STATES DISTRICT JUDGE

MAY 19, 2016

APPEARANCES:

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1 Okay. Oh, that collateral source is granted. I
2 don't think -- that's probably moot. I don't think the
3 Defendants have any problem with this collateral source of
4 other payments made to the parents because of insurance or
5 whatever. I think that was 5.

6 6.

7 Plaintiffs want to exclude the testimony of
8 Dr. Ticknor regarding the adequacy of Depakote's warnings.
9 Hmm? That's denied. That's what the whole case is about.

10 Okay. Here we go. I think that's all of Plaintiffs'
11 motions.

12 Defendant's motions. Okay. Abbott seeks to exclude
13 references to off-label marketing. Yeah. Well, I mean, if
14 you're advertising this product for whatever, maybe it seems
15 it may be relevant. So that's denied.

16 No. 2. Okay. This is about this evidence of
17 promotion of Depakote for treatment of conditions other than
18 bipolar. So Defendants want to exclude this. What will this
19 show? You know, I mean, I think it's got this whole epilepsy
20 thing and so forth. What will this show?

21 MR. BALL: Your Honor, all of those motions, 1
22 through 5, all relate to advertising, marketing, promotion,
23 and what we are trying to do is keep this case within the time
24 limits the Court wants to keep it and try this case. Failure
25 to warn, Dr. Mallya, Ms. Forbes, bipolar -- that's what this

1 case should be about. What the Plaintiffs want to do is try
2 Abbott as a company, and they want to get in evidence that --
3 that allegedly --

4 THE COURT: Sounds like a good strategy to me.

5 MR. BALL: Yeah, but it's not -- it may be -- it may
6 be thought of by the Plaintiffs as a good strategy, but it's
7 not a proper strategy.

8 THE COURT: Well, but, you know, let's get down to
9 the nitty-gritty here on this thing in terms of what you
10 wanted out -- well, maybe we need to talk to Plaintiffs. What
11 is this going to show? I mean, what's this going to show
12 that's relevant to this case?

13 MR. BOUNDAS: Yeah, Your Honor. I mean the first
14 point is that Abbott has moved to exclude things that they
15 call sales and marketing materials, but then if you look at
16 their motion, you don't see what evidence they're trying to
17 keep out. Here's --

18 THE COURT: Well, what evidence are you trying to get
19 in? That's what I'm talking about.

20 MR. BOUNDAS: Yeah. So here's what we're trying to
21 get in, Your Honor. Abbott promoted Depakote as both a
22 bipolar and an epilepsy drug, and they labeled it the exact
23 same for both conditions. They promoted it the same for both
24 conditions, and their sales and marketing department were the
25 same people. So let me give you an example.

1 THE COURT: What difference does that make?

2 MR. BOUNDAS: I'll give you a specific example. We
3 have documents showing when this birth defect information came
4 out, that Abbott says, "Well, 50 percent of our prescriptions
5 are exposed to attack." They're calculating how much money it
6 will cost them.

7 THE COURT: Wait a minute. They're saying, "50
8 percent of our" -- what?

9 MR. BOUNDAS: -- "prescriptions are exposed to
10 attack."

11 THE COURT: Okay.

12 MR. BOUNDAS: Now, I don't know. That could be
13 prescriptions for epilepsy, for bipolar, or both. The point
14 is most of the -- what they call marketing evidence that we
15 want to get in is related to the marketing department's
16 influence and knowledge about the risk of birth defects as it
17 came out and how they influenced that. For example,
18 scientific study comes out. Abbott's marketing department
19 gets ahold of it and edits part of the study to take certain
20 things out. So when doctors get the study, it's different
21 than it was when it came into Abbott. We have evidence that
22 they wanted to promote this as the first choice treatment for
23 women, not just for epilepsy but also for bipolar. So we're
24 keeping this focused on the issue of birth defects, Your
25 Honor. I assure you you're not going to hear anything

1 about -- we're not going to be talking --

2 THE COURT: Well, why are you talking about epilepsy
3 then?

4 MR. BOUNDAS: Because a lot of the -- Depakote has
5 been known for like 30 years as what's known as an
6 antiepileptic drug. Antiepileptic drugs are also used by
7 psychiatrists frequently. So there's no way to untangle a lot
8 of that because some of the documents talk about antiepileptic
9 drugs. Some of the documents talk about bipolar drugs.
10 You're going to see we're not going to be talking about
11 epilepsy and seizures and things like that. This same issue
12 came up in front of Judge Rosenstengel.

13 THE COURT: Now, are you telling me that the
14 marketing people for Abbott changed information that was in
15 the studies when they put it out to the public or to medical
16 personnel?

17 MR. BOUNDAS: Yeah, that's what we're going to put on
18 evidence about.

19 THE COURT: Well -- and what did they change?

20 MR. BOUNDAS: They received the -- what's known as
21 the Holmes study, and the study suggested that women of
22 childbearing age avoid taking Depakote and try safer
23 alternatives, and they chose --

24 THE COURT: Now, that sounds like that is likely
25 relevant. So I don't have a problem with that.

1 MR. BOUNDAS: Yeah. Your Honor, I guess what I'm
2 saying --

3 THE COURT: All of this periphery that you're talking
4 about is -- you know, I'm not interested in that.

5 What do you got to say about this, Mr. Ball?

6 MR. BALL: Your Honor, just a minute ago, in
7 overruling one of our motions, you said that we should kind of
8 focus and not expand this case beyond. Not one iota of
9 evidence they have about our marketing found their way to
10 Dr. Mallya. Okay. There's no evidence that she was
11 influenced by that, that she was -- that that was discussed.
12 So we -- if we're going to -- if, as you ruled before, we're
13 going to talk about this case and up until the time of 2004,
14 then we ought to be talking about what had an effect on
15 Dr. Mallya and what had an effect on bipolar and that type of
16 thing as opposed to running off on tangents. They -- 19 hours
17 of testimony by video deposition.

18 THE COURT: Okay. Okay. Okay. Well, fine. I'm
19 going to inquire momentarily about, you know, what the doctor
20 knew in terms of making this, you know, prescription decision,
21 but, you know, perhaps -- and I don't know, and maybe
22 Mr. Boundas can tell us. Perhaps there is something in that
23 information from the marketing department that says there
24 should have been better labeling. I don't know.

25 Go ahead, Mr. Boundas.

1 MR. BOUNDAS: Yes. Your Honor, you, in your ruling
2 on one of the motions for summary judgment -- I think it was
3 the punitive damages motion -- you noted that we have evidence
4 that a lot of Abbott's decisions to communicate birth defect
5 information were driven by sales and marketing concerns, and
6 what we are going to show is that within the company, the
7 birth defect risk was regarded as an obstacle to selling the
8 product. We're not -- we're -- so what we are going to show
9 is that there were economic motivations for this company to
10 refuse to disseminate this information to the doctors. That's
11 what this evidence shows, and that's what we're focused on,
12 and --

13 THE COURT: Well, does the -- is this evidence going
14 to show that there should have been better labeling? What is
15 it going to show?

16 MR. BOUNDAS: Absolutely, Your Honor, because what it
17 shows is that they have information that would have -- let me
18 give you a concrete example, a study showing 10 percent risk
19 of birth defects, and instead of giving that study out, in the
20 marketing department, they say, "Well, the study is biased.
21 We're going to -- we're going to literally fight like dogs to
22 show that this is a biased study." That shows that they could
23 have communicated this information sooner and that they had
24 it.

25 And I'll add, Your Honor, that Judge Rosenstengel

1 issued a long opinion about this, explaining how a company
2 motivated by financial concerns -- that can affect how they
3 decided to communicate information.

4 We're not talking about things unrelated to birth
5 defects. We're not trying this company on, you know, other
6 things that they have done, of which there's a lot. We're
7 focusing it on what the marketing department knew about birth
8 defects, how they reacted to it, and how that led them to
9 choose not to communicate this.

10 THE COURT: What say you, Mr. Ball, about this?

11 MR. BALL: Okay. This 19 hours of deposition
12 testimony they have, which cover Motions in Limine 1 through 5
13 is far beyond what he just talked about. There's things in
14 there about --

15 THE COURT: Well, we're not going to deal with all
16 those things. We're going to deal with what Mr. Boundas was
17 talking about.

18 MR. BOUNDAS: Yeah, Your Honor. Just to clarify, we
19 don't have 19 hours. Every deposition we want to play from
20 every category with every witness, the total, I think, is
21 eight hours.

22 THE COURT: I don't care how long they are. What I'm
23 talking about is that what you told me -- that would be the
24 evidence that you would be putting on -- how they had
25 information that they could or should have passed out to the

1 medical community and perhaps changed their labeling. That's
2 it.

3 MR. BOUNDAS: That's what we are focusing on.

4 THE COURT: Is our focus good?

5 MR. BALL: Are we going beyond bipolar then? Because
6 a lot of what they have gets into epilepsy. They have
7 evidence of schizophrenia.

8 THE COURT: Now, I don't want anything about any
9 epilepsy. Why?

10 MR. BOUNDAS: The only thing -- if it relates to a
11 risk of birth defects, we want to put it on. If it's just
12 about epilepsy, we have no intention of -- I agree with them.
13 But if they have a study that shows that people with epilepsy
14 and bipolar are getting birth defects, I don't see how that's
15 not relevant. We're not going to --

16 THE COURT: Well, suppose they've got a study that
17 just shows people with epilepsy having children with birth
18 defects?

19 MR. BOUNDAS: Same thing because --

20 THE COURT: I don't know about that one.

21 MR. BOUNDAS: Well, Your Honor, Abbott has taken the
22 position that it's the exact same chemical, whether a bipolar
23 woman takes it, a woman with migraines, a woman with epilepsy.

24 THE COURT: I understand that, but I'm inclined for
25 you to limit your studies because we don't have anybody in

1 this case with epilepsy. All we've got is bipolar.

2 MR. BOUNDAS: But, Your Honor, the risk of birth
3 defects is dependent on a lot of the studies that had to do
4 with epileptic women because the drugs went on the market, for
5 the most part, for women with epilepsy. So if they -- let me
6 give you an example. If they know that women with epilepsy
7 are getting birth defects at a rate of 25 percent -- we have a
8 study that says that -- well, that goes without saying that
9 that would be relevant to a psychiatrist to know that 25
10 percent of the women that she might give this drug to can have
11 birth defects, whether it's epilepsy or bipolar. And their
12 own expert has admitted that. It doesn't matter what the
13 women is taking the drug for. The fetus doesn't know that.
14 And so we're only -- Your Honor, I can assure you we are not
15 trying an epilepsy case. We're trying a birth defect case.

16 THE COURT: Okay. Mr. Ball, what do you got to say
17 about that?

18 MR. BALL: So let me just give you a couple. In
19 addition to not being tied at all to Dr. Mallya -- she
20 never -- they never showed, "If you had known this marketing
21 information, would you have said something differently?" They
22 don't have any tie like that. Okay.

23 THE COURT: Well, you're going to ask her that.
24 So --

25 MR. BALL: But number two is Depakote was not even

1 indicated or taken for -- excuse me -- "approved" is the word
2 I was looking for -- approved for the bipolar disease until
3 1996. Yet some of what they want to show is when it was only
4 approved for epilepsy. This is how broad these deposition
5 excerpts and these exhibits they have attached to those --

6 THE COURT: What about that? You got something --
7 all your -- you got post-'96 studies?

8 MR. BOUNDAS: We do have post-'96 studies, yes.

9 THE COURT: Well, why don't we limit it to post-'96
10 studies? Does that work?

11 MR. BOUNDAS: That works.

12 THE COURT: That's that.

13 MR. BALL: Well, that takes care of that argument.
14 So we won that one. That would be No. 4.

15 So, you know, our general thing is this case ought to
16 be about Dr. Mallya and bipolar and spina bifida. That's what
17 it ought to be about. They want it to be about far broader
18 than that.

19 THE COURT: Well, please. I'm through with this.
20 I'm going to allow in post-'96. Okay.

21 MR. BALL: And you said it also had to relate to the
22 risk of birth defects. That was the other thing you said,
23 right?

24 THE COURT: Yes.

25 MR. BALL: Yeah. Okay.